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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/28/2003

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12/26/2008

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

12/26/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NYIPDocket@arentfox.com
Patent_Mail@arentfox.com

DETAILED ACTION

1. Applicants' Response to Office Action, received 12 September 2008, is acknowledged.
2. Claims 1-6, 8-38, and 40-47 are pending. Claims 20, 23-28, and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
3. Claims 1-6, 8-19, 21, 22, 29-38, and 40-46 solely drawn to a method and kit for diagnosis of TSE using polypeptide are under consideration.

Rejection Maintained

4. The rejection of claims 29-31 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of "probe", is maintained.

Applicants argue that "probe" is described in the specification, paragraph 00044, as a probe that "may consist" of a strip having several absorbent wells and "may have" hydrophobic, strong anionic or weak cationic exchange surfaces under condition which allow binding polypeptides.

The examiner has considered applicants' argument, but does not find it persuasive. The cited paragraph, which giving an example, does not define what the metes and bounds are for a "probe".

5. The rejection of claims 1-6, 8-19, 21, 22, 29-38, and 40-46 under 35 U.S.C. 112, first paragraph, scope of enablement for differentiation of any/all forms of TSE by mere alteration of level of nonspecified proteins, is maintained.

Applicants argue that claims 2, 3, 12-15, 32, 33, 35-37, 40 and 43 recite that the reference amount is specifically described as being present in the body fluid of a subject that either does, or in some cases, does not have BSE or CJD and therefore the rejection does not apply to these claims.

Art Unit: 1645

The examiner has considered applicants' argument, but does not find it persuasive. Claim 1 recites that "wherein an increase or decrease in the polypeptide in the subject's body fluid compared to the reference indicates BSE or CJD in the subject". In the embodiment of group C, it is put forth that a hemoglobin fragment is indicative of BSE or CJD. However, it remains unclear how one distinguishes BSE or CJD samples from a normal subject's sample of serum or plasma which would also contain hemoglobin fragments.

Applicants argue that one skilled in the art would understand that the size of signal of the protein peaks is compared with diseased and healthy samples to identify the discriminatory species.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection. In addition, the claims do recite that the discrimination is dependent on the size of the signal, only that an "increase or decrease" in the polypeptide is indicative. There remains no cut-off values for discriminating between diseased and healthy subjects.

Conclusion

6. No claims are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

Art Unit: 1645

will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 20,23-28 and 47 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 18, 2008